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The time period for reply, if any, is set in the attached communication.

1 RECORD OF ORAL HEARING

2
3 UNITED STATES PATENT AND TRADEMARK OFFICE

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5
6 BEFORE THE BOARD OF PATENT APPEALS
7 AND INTERFERENCES
8

9
10 Ex parte MELTON B. AFFRIME, CHRISTOPHER R. BANFIELD,
11 SAMIR K. GUPTA and DESMOND PADHI
12

13
14 Appeal 2007-3897
15 Application 09/760,588
16 Technology Center 1600
17

18
19 Oral Hearing Held: February 12, 2008
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22
23 Before TONI R. SCHEINER, ERIC GRIMES, and JEFFREY N.
24 FREDMAN, *Administrative Patent Judges*.
25

26 ON BEHALF OF THE APPELLANTS:

27
28 PAUL J. BERMAN, ESQ.
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35 The above-entitled matter came on for hearing on Tuesday, February
36 12, 2008, commencing at 9:24 a.m., at the U.S. Patent and Trademark
37 Office, 600 Dulany Street, Alexandria, Virginia, before Carol A. Lowe,
38 RPR, CCR No. 0313084, Notary Public.

1 JUDGE SCHEINER: Good morning.

2 MR. BERMAN: Good morning.

3 JUDGE SCHEINER: Would you like to introduce your -- well,
4 first let me tell you we have an observer this morning.

5 MR. BERMAN: Good morning.

6 JUDGE SCHEINER: And would you like to introduce your
7 colleagues for the record?

8 MR. BERMAN: I would be pleased to. I'm Paul Berman from
9 Covington & Burling. This is my colleague, Natalie Derzko, also from
10 Covington & Burling. Henry Haddad and Barry Jacobson from the assignee,
11 Schering-Plough Corporation. And another colleague, Brook Harper, from
12 Covington & Burling.

13 JUDGE SCHEINER: Good morning.

14 MR. BERMAN: Thank you very much.

15 JUDGE SCHEINER: Whenever you're ready. You have 20
16 minutes.

17 MR. BERMAN: Thank you. May it please the Board. This is
18 a pure inherent anticipation case solely under Section 102(e) of the statute
19 with respect to a single reference, the 274 patent to Kou which is also owned
20 by the assignee Schering.

21 A terminal disclaimer has been filed to obviate any
22 obviousness-type double patenting rejection to avoid even the appearance
23 that this is a pharmaceutical company trying to Evergreen its patents.

24 Because the Kou reference and this application are commonly
25 owned this application is entitled to the benefit of Section 103(c) of the
26 statute of the patent code in this regard.

1 We did exactly what the statute encourages in the context of a
2 very difficult and challenging drug development problem. It turns out that
3 desloratadine, the active ingredient in the Kou formulation, is a very active
4 molecule and degrades in the presence of certain excipients. The Kou
5 invention is directed to and claims formulations that solve that degradation
6 problem.

7 What Schering did was to proceed to file a patent application on
8 the formulation that's the Kou patent rather than waiting for the necessarily
9 subsequent clinical trials that would develop a safe and effective
10 pharmacokinetic profile.

11 We could have waited to file both inventions, if you will, in the
12 same application. We thought we were protected by 103(c) and that 103(c)
13 encouraged us to file the formulation patent first which we did.

14 If we had waited to file them at the same time, there would be
15 no prior art Kou reference at all. We believe that we're being penalized
16 unfairly and wrongly for having engaged in a course of conduct that the
17 statute encourages.

18 The invention of this application really is the discovery of a
19 target pharmacokinetic profile that would be safe and effective. Once the
20 skilled clinician has that profile which is entirely missing from the prior art
21 Kou reference, then she would know what to do in light of the relevant
22 factors to target it. These factors include -- yes.

23 JUDGE SCHEINER: Can I interrupt for just a second?

24 MR. BERMAN: Please.

25 JUDGE SCHEINER: The claim -- now, I understand that this -
26 - Kou is the stabilized desloratadine. But the original patent on this was

1 Vilani; is that correct?

2 MR. BERMAN: Yes.

3 JUDGE SCHEINER: Now, would that have the same PK
4 profile?

5 MR. BERMAN: Not necessarily.

6 JUDGE SCHEINER: Not necessarily. Is it -- okay.

7 JUDGE FREDMAN: Is it the same molecule?

8 MR. BERMAN: I'm sorry.

9 JUDGE FREDMAN: Is Vilani the same molecule,
10 desloratadine?

11 MR. BERMAN: The Vilani claims the same molecule,
12 desloratadine, as we're talking about here but different formulation.

13 JUDGE SCHEINER: But my question is if the -- now, the
14 claim on its -- at first glance just says desloratadine. It doesn't -- I
15 understand that your specification references the Kou patent for -- that -- that
16 the -- the clinical trials that are described in the specification were done with
17 the formulation that's described in the Kou patent.

18 MR. BERMAN: Yes.

19 JUDGE SCHEINER: But the claim apart from these -- leaving
20 aside for a moment the PK profile, the claim just says desloratadine. It's not
21 a particular -- it doesn't recite a particular formulation.

22 So my question is whether or not the desloratadine that's
23 described in the original application, the Vilani, would have that same PK
24 profile.

25 MR. BERMAN: Not necessarily. There are a range of factors
26 that the skilled clinician would need to take into account in order to target

1 the specified pharmacokinetic profile.

2 JUDGE SCHEINER: Okay.

3 MR. BERMAN: These include the dosage amount, the dosage
4 size which is not specified in Vilani at all, the number of administrations per
5 day, the weight and age of the patient as well as the pharmacokinetic
6 characteristics of desloratadine on which Kou and, parenthetically, Vilani
7 are silent and which are taught by this application; that desloratadine has
8 lineal pharmacokinetics and exhibits dose proportionality example.

9 With that information and those factors a skilled clinician
10 would be able to target a pharmacokinetic profile.

11 JUDGE SCHEINER: Well, let me ask you. Also, I notice that
12 originally in this case the claims were all directed to producing this
13 particular PK profile. And somewhere along the line it became targeting the
14 profile. Can you elaborate on that a bit?

15 MR. BERMAN: I can elaborate on that. The primary reason
16 for that, Your Honor, is that with respect to any method of administration
17 claim, whether the claim be phrased as a method for treating something or a
18 method for targeting something, the skilled clinician is striving for a result
19 which may or may not be achieved. It's -- they're all goal oriented claims.
20 And --

21 JUDGE SCHEINER: Well, are we talking about a mental step
22 here? If you don't intend to target this profile, you're not within the scope of
23 the claim?

24 MR. BERMAN: It's more than a mental step. It requires
25 administration here. And that's -- each one of the claims requires
26 administering a pharmaceutical composition or formulation comprising

1 desloratadine to -- for the purpose of targeting a particular --

2 JUDGE SCHEINER: And the specification indicates that five -
3 - five mgs per day in single dose or divided doses will accomplish that or
4 will produce that profile. Is that correct?

5 MR. BERMAN: Not necessarily. It will in some people, but in
6 others it will not.

7 JUDGE SCHEINER: Okay.

8 MR. BERMAN: Let me give you -- some examples include
9 age of the patient, whether -- and you indicated five milligrams once a day.
10 The specification also teaches two-and-a-half milligrams in -- twice a day,
11 other divided doses which would surely result in a different pharmacokinetic
12 profile.

13 In addition, note that a single administration as another example
14 provides a time to maximum concentration of four hours whereas in the
15 steady state the T max is three hours.

16 As another example, this specification teaches that for elderly
17 people over 65 the half-life is about 30 percent longer.

18 So depending on these factors a different pharmacokinetic
19 profile would result. And a skilled clinician would be able to take these
20 factors into account to achieve the specified, claimed pharmacokinetic
21 profile.

22 JUDGE FREDMAN: From the point of inherent anticipation
23 the question I would wonder is -- the drug was available in 1990. When did
24 this drug first come out?

25 MR. BERMAN: It was subsequent to these applications. If
26 you'll excuse me --

1 JUDGE FREDMAN: The desloratadine was not available
2 before 2000?

3 MR. BERMAN: No. It was approved in 2001.

4 JUDGE FREDMAN: So loratadine was earlier but not
5 desloratadine.

6 MR. BERMAN: Yes. That's correct.

7 JUDGE SCHEINER: Okay.

8 MR. BERMAN: And -- yes. Loratadine is Claritin.

9 JUDGE FREDMAN: Right.

10 MR. BERMAN: And Desloratadine is --

11 JUDGE FREDMAN: Clarinex.

12 MR. BERMAN -- Clarinex.

13 JUDGE SCHEINER: Clarinex.

14 JUDGE FREDMAN: Okay.

15 JUDGE SCHEINER: So it wasn't then.

16 MR. BERMAN: It was not.

17 JUDGE SCHEINER: Okay.

18 MR. BERMAN: Again, this is prior art only under 102(e).

19 JUDGE SCHEINER: Okay.

20 MR. BERMAN: Thank you. I appreciate that.

21 JUDGE SCHEINER: But the earlier formulation was not
22 available either. I understand that this desloratadine is Clarinex, but the -- I
23 assume that's with the -- as formulated in Kou.

24 MR. BERMAN: Correct. Desloratadine --

25 JUDGE SCHEINER: And it wasn't available -- desloratadine
26 was not --

1 MR. BERMAN: Not available --

2 JUDGE SCHEINER: -- available before 2001.

3 MR. BERMAN: Right.

4 JUDGE SCHEINER: Okay.

5 MR. BERMAN: This is a different invention from Kou. Kou
6 is to a formulation, not a method of administration. Formulations and
7 methods of administration have been separately patentable for a long, long
8 time. And we believe that the examiner's decision would upend this settled
9 aspect of patent law.

10 The logic of the examiner's decision would have the Kou
11 disclosure which is silent on pharmacokinetics, silent on the behavior of
12 loratadine in the body anticipate -- not just render obvious but anticipate all
13 dosage regimens for the Kou formulation. That can't be the case.

14 In addition, Kou says nothing about duration, how many days,
15 which provides an additional reason why claim 73, 74, 75 and 82 are
16 patentable over Kou since each of them specifies about 10 days.

17 We believe that the examiner's error is clear from what she says
18 at page 6 of her answer. And I quote. Thus, the Kou 274 patent would
19 anticipate these claims wherein there is a dosage of five to 10 milligrams per
20 day administered in a single or divided dose and the course of the precise
21 dosage regimen may be varied depending on the requirements of the patients
22 as well as the severity of the allergic condition being treated.

23 But the target is provided by the present application, not by the
24 Kou reference. And once a skilled clinician has a target she can decide
25 whether to administer five or 10 mgs per day or something in between in
26 single or divided doses or decide on a different, quote, precise dosage

1 regimen.

2 The examiner's statement makes our point in other ways as
3 well. Her statement says nothing about steady state; says nothing about the
4 duration of treatment; says nothing about the weight of the person and even
5 for a single day's worth of administration would result in at least four, if not
6 more, pharmacokinetic profiles.

7 The examiner's problem is also highlighted by the penultimate
8 sentence at the end of the paragraph. And I quote again. Once a reference
9 teaching a product appearing to be substantially identical is made the basis
10 of a rejection and the examiner presents evidence or reasoning tending to
11 show inherency -- parenthetically, which we don't think she's done -- the
12 burden shifts to the appellant to show an unobvious difference.

13 The burden has not shifted to us to show an unobvious
14 difference. This is not an obviousness case. It's an anticipation case. The
15 test is whether the claimed invention necessarily results from the teaching of
16 the prior art reference. Probabilities and possibilities do not suffice.

17 And the Kou reference says nothing about and does not
18 necessarily result in the target pharmacokinetic profile that is central to each
19 of the pending claims. Thank you.

20 JUDGE SCHEINER: Do you have anything? Any questions?
21 Thank you for coming in.

22 MR. BERMAN: Thank you.

23 (Whereupon, the proceedings at 9:37 a.m. were concluded.)
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